

**K190167 MitraClip G4 Steerable Guide Catheter**May 29, 2019  
118 days to decisionK190167 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190167/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Jan 31, 2019
Decision date	May 29, 2019
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Abbott</b>
Location	St. Paul, MN, US
Contact	Ekta Lad
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	12 submissions · 12 cleared · 2018-2026

Abbott is a global healthcare company developing life-changing medical devices and solutions. The company operates with a manufacturing facility in St. Paul, Minnesota. Abbott serves patients across multiple therapeutic areas including diabetes care, nutrition, diagnostics, and cardiovascular health. Abbott has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Cardiovascular devices, which represent 91% of its FDA 510(k) portfolio. Abbott's first clearance was granted in 2018, with the mo...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190167/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026